

# Exhibit 138

*United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.*

Civil Action No. 07-10248-PBS

Exhibit to the July 24, 2009, Declaration of James J. Fauci  
In Support of Plaintiff's Motion for Partial Summary Judgment and  
In Opposition to the Roxane Defendants' Motion For Partial Summary Judgment

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August 20, 1999

HAND DELIVERY

The Honorable Tom Bliley  
Chairman, Committee on Commerce  
U.S. House of Representatives  
Room 2126  
Rayburn House Office Building  
Washington, D.C. 20515-6115

Re: Response to Request for Pricing Information, July 19, 1999

Dear Mr. Chairman:

We are writing as counsel on behalf of Bedford Laboratories in response to your letter of July 19, 1999, to Thomas Russillo, in which you request certain information and documents regarding the pricing of Bedford's products generally, and, specifically, its pricing for the generic product, Leucovorin, 50 mg. Since receiving your letter, we have spoken with Mr. Charles Clapton, Committee Counsel, and have obtained from him a necessary extension of the time for responding to your request for this information. We are grateful for the courtesy shown us by Mr. Clapton and for your patience in awaiting our response.

Set forth below are your questions/requests and the responses of Bedford Laboratories.

1. Please provide all definitions of AWP used by your company since January 1, 1996 for the purpose of determining the reimbursement price for Medicare-covered drugs, and all records relating to those definitions. In particular, please provide the specific definitions you apply to the terms "average" and "wholesale."

Answer: The term "AWP", which we interpret as meaning Average Wholesale Price, is not used by Bedford Laboratories in pricing any of its products. Moreover, Bedford has not and does not take into account the "reimbursement price for Medicare-

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covered drugs" in pricing any of its products. Rather than use AWP, Bedford establishes a Hospital List Price for its products. The Hospital List Price refers to the price a customer without a contract, who is not a wholesaler or distributor, would pay for Bedford's products. It also refers to a suggested price that a wholesaler charges its customers. This terminology is used because the majority of Bedford's customers, particularly for drugs such as Leucovorin, are hospitals.

The pharmaceutical reporting services, such as Redbook, independently identify Bedford's Hospital List Price as AWP. The prices Bedford charges its wholesale customers are referred to at Bedford as Wholesale List Prices, which are identical for all of Bedford's wholesale customers. These prices are identified by the pharmaceutical reporting services as Wholesale Acquisition Cost ("WAC"). Given its pricing terminology and practices, Bedford's definitions of the terms "average" and "wholesale" are the standard dictionary definitions.

2. Please explain the methodology used by Bedford Labs, or any other entity acting on Bedford Labs's behalf, to calculate the specific AWP for Leucovorin per 50 mg during Calendar Year (CY) 1998.

Answer: As indicated above, AWP is not used at Bedford. Accordingly, Bedford performs no AWP calculation for Leucovorin, 50 mg and did not do so during calendar year 1998. Rather, Bedford's Hospital List Price for Leucovorin, 50 mg for calendar year 1998 was the same throughout the years 1996-1998 -- \$184.40 per 10 vial unit. This price was established by Chiron Therapeutics, which prior to May, 1996, had the marketing responsibilities for this product. Bedford took over those responsibilities in May of 1996 and continued the price established by Chiron. Prior to that time, Ben Venue, Bedford's parent, only manufactured this product. For that reason, Bedford is not aware of how Chiron originally priced this product.

3. Please identify any changes that have been made to the method of calculating the AWP for Leucovorin per 50 mg since the OIG's December 1997 report.

Answer: Since the publication of the OIG's December 1997 report, titled "Excessive Medicare Payments for Prescription Drugs", Bedford has made no change in the price or the method of calculating its Hospital List Price for Leucovorin, 50 mg.

4. Please identify the average annual AWP for Leucovorin per 50 mg in CY 1998 as well as in the preceding two calendar years.

Answer: Bedford's Hospital List Price, which as indicated above is reported by the Redbook and other pharmaceutical reporting services as AWP, was \$184.40 for a 10 vial unit for CYs 1998, 1997 and 1996.

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5. Please provide the actual prices Bedford Labs charged for Leucovorin per 50 mg to every wholesale customer during CY 1998 and for each of the preceding two calendar years. In responding to this request, please take into account any rebates, discounts or free goods provided by Bedford Labs that would affect the actual per-unit price charged to that customer. In addition, Bedford Labs need not provide any information identifying the particular customers who purchased Leucovorin, or the volume of Leucovorin sold to the customers for the stated per-unit price.

Answer: During CY 1998, Bedford charged the same price to each of its wholesale customers for Leucovorin, 50 mg. That price was \$30.00 per 10 vial unit. For CY 1996 and 1997, Bedford's price for that same product for its wholesale customers was \$60.00.

Bedford offered no rebates, discounts or free goods to any of its wholesale customers with respect to Leucovorin for those years. However, Bedford did offer a two percent prompt payment discount to its wholesale customers for cash payments made within 30 days of the invoice date. This prompt payment discount was not tied to any particular product, but related to prompt payment for each invoice.

Although not requested, we want you to be aware that Bedford also markets its products to distributors, group purchasing organizations ("GPOs") and contract customers. Some of those distributors pay the Wholesale List Price for Bedford's products, while other distributors, usually specialized ones, pay a Distributor Acquisition Cost ("DAC") and participate in Bedford's chargeback system, as do wholesalers. Chargebacks are the monetary credits given distributors/wholesalers who distribute products to Bedford's contract customers, and represents the difference between the prices paid by the distributor/wholesaler for the products and the prices its customer had previously negotiated with Bedford. GPOs and other individual accounts will negotiate directly with Bedford on product pricing. In those contexts, the prices set by Bedford for its products are the result of negotiations and the existing or expected competitive environment.

From December, 1996 to the present, the DAC for Leucovorin, 50 mg has been \$25.00 per 10 vial unit, while the prices for this product for Bedford's contract customers during that same period have been in the range of \$16.50 to \$36.00 per 10 vial unit. During the period 1996-1998, Bedford's contracts did not contain rebate, discount or free good provisions related specifically to this product. However, for contract customers, there may have been administrative fees paid to them for total volume purchases.

6. Please provide all records relating to communications between Bedford Labs and any medical provider or group of providers since January 1, 1996 that relate to the AWP for Leucovorin per 50 mg.

Answer: Bedford has no records relating to communications between itself and any

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medical provider or group of providers since January 1, 1996 that relate to AWP for Leucovorin, 50 mg. Bedford published annual price lists for its products for those years, as well as promotional materials for its oncology line of products, which would include Leucovorin, 50 mg. Copies of those documents are enclosed, marked as BL 00001-00131.

We hope the information set forth above and the enclosed documents are helpful to you. If you have any questions regarding any of the responses or the enclosed documents, or need any additional information, please contact us at your earliest convenience.

Sincerely,

Paul J. Coval  
Richard J. Leon

jmp

Enclosures

cc: Thomas Russillo  
bcc: Bruce L. Banks, Esq.  
James R. Kennedy, Esq.  
Douglas L. Rogers, Esq.